Patent App. Ser. No. 10/768,728 Eclipse Group Docket No. INM08007USU

<u>REMARKS</u>

Claims 13-17 and 20 are pending in this present application. In the October 26, 2009 Non-Final Office Action, the Examiner:

- Rejected claims 13 and 14 under 35 U.S.C §103(a) as being unpatentable over Pieronne et al. (U.S. Patent No. 4,662,355) in view of Leschinsky et al. (U.S. Patent No. 5,439,448) and further in view of Rawles et al. (U.S. Patent No. 6,890,316);
- 2. Rejected claims 15 and 20 under 35 U.S.C. §103(a) as being unpatentable over (Pieronne et al. in view of Leschinsky et al. in view of Rawles hereinafter "Modified Pieronne") and further in view of Aboul-Hosn et al. (U.S. Patent No. 6,935,344).
- 3. Rejected claim 16 under 35 U.S.C. §103(a) as being unpatentable over (Pieronne et al. in view of Leschinsky et al. in view of Rawles hereinafter "Modified Pieronne") as applied to claim 13 above, and further in view of Runge (U.S. Patent No. 5,743,845); and
- 4. Rejected claim 17 under 35 U.S.C. §103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. in view of Rawles and Runge as applied to claim 16 above, and further in view of Aboul-Hosn et al.

Claims 13-17 and 20 presently stand rejected. Applicants traverse these rejections. Reconsideration of the pending claims is respectfully requested.

I. INDEPENDENT CLAIM 13 IS NOT OBVIOUS OVER PIERONNE IN VIEW OF LESCHINSKY, AND FURTHER IN VIEW OF RAWLES

The Examiner rejected Claims 13 and 14 under 35 U.S.C §103(a) as being obvious over Pieronne et al. (U.S. Patent No. 4,662,355) in view of Leschinsky et al. (U.S. Patent No. 5,439,448) and further in view of Rawles et al. (U.S. Patent No. 6,890,316). The Examiner's rejections are repeated from previous office actions.

Applicants have amended claims 13 and 20 to more clearly recite the fact that priming the shunt requires no fluid other than the patient's own blood received from the patient during the surgical connection of the shunt "by allowing the blood to fill the shunt

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to remove air through open vents." That is, no other liquid, such as saline or donor blood or the patient's own blood, is added to the shunt or any other tubing during surgical attachment.

Rawles does not teach priming the blood handling system "with the patient's own blood by allowing the blood to fill the shunt to remove air through open vents" as recited in claim 13. (emphasis added). Rawles teaches that the blood handling system is initially primed with saline "until all air bubbles are removed from all lines and the integrated blood pump/oxygenator 41." Rawles 9:20-21. Rawles also teaches that "only approximately 400 to 500 ml of priming fluid are required." Rawles 9:7-8. (emphasis added). The saline, not the blood, removes "all air bubbles." The blood displaces the saline and directs the saline to a bag once the blood pump is coupled to the cannulae. See Rawles 9:22-27. Rawles clearly teaches adding a liquid, such as saline or donor blood or previously collected patient blood to prime the blood handling system.

The Examiner's argument that the claim is written in open-ended format exalts form over substance. Applicants respectfully submit that the Examiner's argument ignores the plain language of independent claim 13, which states: "priming the shunt with the patient's own blood by allowing the blood to fill the shunt to remove air through open vents." The claim is written in open-ended format. Accordingly, steps that are not recited may be added in an implementation of the method. However, adding a step that violates a recited step is not permitted. A step in which saline or the patient's own previously collected blood is added to the blood handling system in order to prime the system would violate the recited step of "priming the shunt ... by allowing the blood to fill the shunt to remove air through open vents."

Applicants have amended claim 13 to further clarify that no liquid is added for purposes of priming the shunt. No new matter is added as the subject matter is disclosed in, at least, paragraphs [0031]-[0034].

Pieronne also does not teach priming the shunt, and particularly, "priming the shunt using the patient's own blood by allowing the blood to fill the shunt to remove air through open vents." Pieronne teaches "[m]eans connected to the bubble detector 6 of the left system circuit for stopping the pump 7 should bubbles be detected." See Pieronne,

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3:12-14. That is: Pieronne teaches stopping the pump if bubbles are detected. Pieronne teaches using air purges in conjunction with input ports for injecting products such as heparine and protamine into the blood circuit. Pieronne does not teach any steps for attaching the blood circuit to the patient nor any steps for priming the blood circuit. The Examiner argues that "air purges" by definition allow the air to escape through the ports. However, that is not the same as a teaching of "priming the shunt"

Neither Pieronne nor Rawles, alone or in combination, teaches "priming the shunt with the patient's own blood to remove air." Therefore, Applicant believes that claim 13 is allowable and the Examiner's rejections should be withdrawn. Additionally, since dependent claims 14-17 depend off of independent claim 13, all the limitations of claim 13 are also limitations on dependent claims 14-17. As such, Applicant also believes that claims 14-17 are also allowable and the Examiner's rejections should be withdrawn.

II. INDEPENDENT CLAIM 20 IS NOT OBVIOUS OVER PIERONNE IN VIEW OF LESCHINSKY, AND IN VIEW OF RAWLES AND FURTHER IN VIEW OF ABOUL-HOSN

The Examiner rejected Claims 15 and 20 under 35 U.S.C. 103(a) as being obvious over Pieronne et al. (U.S. Patent No. 4,662,355) in view of Leschinsky et al. (U.S. Patent No. 5,439,448) in view of Rawles et al. (U.S. Patent No. 6,890,316) hereinafter "Modified Pieronne") and further in view of Aboul-Hosn et al. (U.S. Patent No. 6,935,344). In the Applicants' response to the Non-Final Office Action, Applicants stated that independent Claim 20 is allowable for the same reasons as claim 13 above. In the October 26, 2009 Non-Final Office Action, the Examiner failed to provide any response to the Applicants' argument specific to independent claim 20. Moreover, claim 20 has been amended as claim 13 above. As such, Applicant believes that claim 20 is allowable for the same reasons as claim 13 and the Examiner's rejections should be withdrawn.

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CONCLUSION

Favorable consideration is respectfully requested in view of the foregoing

amendments and remarks.

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